SUN BIOMEDICAL LABORATORIES, INC.

604 VPR CENTER, 1001 LOWER LANDING ROAD, BLACKWOOD, NJ 08012
Tel. 856-401-1080 Fax. 856-401-1090

MAR 2 0 2002

K020136

510(k) CONTENT SUMMARY

1. Name of Manufacturer:

   Sun Biomedical Laboratories, Inc.
   604 VPR Center
   1001 Lower Landing Road
   Blackwood, NJ 08012

2. Trade Name: Visualine® Barbiturates DipStripTest

3. Common Name:

   An in-vitro immunoassay test by visual color comparison for the detection of Barbiturates and it's metabolites in human urine samples. **This test is intended for professional use only.**

4. Regulation # and Classification:

   Reg. #862-3150, Class II Device

5. Test Description:

   The Visualine® Barbiturates DipStripTest is based on the principle of antigen-antibody complexation and is used for the analysis of Barbiturates and it's metabolites in urine samples. The assay utilizes a competitive immunochromatographic technique involving a sample of test urine delivered in a sample well on the device that holds the porous membrane. When the drug is present in the urine test sample, the drug or drug metabolite competes for the limited antibody sites on the colored microspheres. When an adequate amount of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored microspheres to the probe site on the membrane. Therefore, a positive urine sample will inhibit the formation of precipitin at the probe site.

   A reference or control line with a secondary antibody reaction is added to the membrane strip to indicate viability of the test. This control line should always be present. A negative urine sample will produce two colored lines and a positive urine sample will show only one, the control line.

6. Comparison of Two Test Systems for Correlation Studies:

The Visualine® Barbiturates DipStrip Test assay is correlated to the Hitachi Emit Barbiturates Assay. The following table illustrates the similarities and differences between the two assays.

	Hitachi® Barbiturates Assay	Visualine® Barbiturates DipStrip Test
Test Principle	Homogenous enzyme immunoassay	Competitive binding immunoassay
Sample/Sample Size	200 *u*L urine	Approx. 150 *u*L (3 drops) urine
Antibody	Polyclonal	Polyclonal
Tracer	Drug-Glucose-6-Phosphate Dehydrogenase	Ab Colloidal Complex
Detection Method	Change in absorbance (ΔA) value detected spectrophotometrically	Visual color precipitin formation
Test Run Time	10-20 minutes, dependent on test	5 minutes
Storage Requirement	2-8°C (36-46°F)	2-30°C (36-86°F)
Detection Level	300 ng/ml Barbiturates	300 ng/ml Barbiturates
Ancillary Equipment	Hitachi Emit Calibrators	none

7. Visualine® Barbiturates DipStrip Test Performance Characteristics

A. Correlation studies between Hitachi Barbiturates Assay and Visualine® Barbiturates DipStrip Test were conducted at Sun Biomedical Laboratories with samples provided by The Lab, Inc. Correlation with Hitachi EmitII® Barbiturates Assay with cutoff at or above 300 ng/ml Barbiturates yielded the following data:

Sensitivity	95 / 101	=	94 %
Specificity	95 / 100	=	95 %
Efficiency	190 / 201	=	95 %

B. Specificity and Substances Detected:
The test is specific to Barbiturates or structurally related compounds.
The test detects Barbiturates at a concentration of 300 ng/ml.

C. Visualine® Barbiturates DipStrip Test Sensitivity:
The sensitivity at 360 ng/ml Barbiturates read at 5 minutes is 94%.

D. Precision: Reproducibility studies indicate:

Within run and run to run	> 99 %
Within day and day to day	> 99 %
Within lot and lot to lot	> 99 %

E. Analytical Studies versus precision and accuracy studies:
The Visualine® Barbiturates DipStrip Tests detect barbiturates at a cutoff of 300 ng/ml.

F. Stability Statement:

Visualine® Barbiturates DipStrip Test stability has been studied. The drug urine tests are tested every three months for up to a period of two years. Visualine® Barbiturates DipStrip Test Kits are stable within their marked expiration date and under the storage conditions as described in the insert.

8. Attachments:

Correlation Studies	(Accuracy)	**Section A**
Specificity Studies	(Interference substances and cutoff level of Barbiturates detectable by Barbiturates test)	**Section B**
Sensitivity Studies	(Analytical studies)	**Section C**
Reproducibility Studies	(Precision)	**Section D**
Visualine® Barbiturates DipStripTest Package Insert		**Section E**
Label Copies		**Section F**
Hitachi Emit Barbiturates Assay Insert		**Section G**
Stability Study		**Section H**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 0 2002

Ming Sun, Ph.D.
President
Sun Biomedical Laboratories Inc.
604 VPR Center
1001 Lower Landing Road
Blackwood, NJ 08012

Re: k020136
Trade/Device Name: Visualine® Barbiturates DipStrip Test
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: Class II
Product Code: DIS
Dated: January 11, 2002
Received: January 15, 2002

Dear Dr. Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SUN BIOMEDICAL LABORATORIES, INC.
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510 (k) Number: K020136

DEVICE NAME: Visualine® Barbiturates DipStrip Test

INDICATIONS FOR USE: The Visualine® Barbiturates DipStrip Test is used for qualitative testing for the presence of Secobarbital in urine samples at or above300 ng/ml. This test provides only a preliminary screening result; a more specific alternative method should be used to confirm the test result. This test is intended for use by medical professionals.

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K020136

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter-Use _____

(Per 21 CFR 801.109) OR (Optional Format 1-2-96)